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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,031	01/11/2002	Stephen F. Badylak	3220-69262	9094

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INDIANAPOLIS, IN 46204

EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/044,031	BADYLAK ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/6/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Abraham et al (US 5,993,844). Abraham anticipates the claim language where Abraham states that the final product is “endotoxin free” such that it is within the claimed range of less than 12 endotoxin units per gram; see column 8, line 55 to column 9, line 13 and column 4, line 49 to column 5, line 6.

The effective filing date of the present claims is August 22, 1997 because support for the range of “an endotoxin level of less than 12 endotoxin units per gram” is not present in either provisional application 60/024,693 or 60/024,542. Rather, the apparently narrower range of “essentially zero bioburden level” is supported in these applications.

In addition, present claims 4-6 do not have support from the provisional applications because there is no clear mention of the number of colony forming units thereof. Furthermore, claim 13 does not have clear support from the provisional applications; see page 2, line 19 of 60/024,693. Additionally, claims 9 and 15 have features that are not supported by the provisional applications.

With regard to support for claim 3 in provisional application 60/024,542, the Examiner concluded that support is lacking because although "5 EU/g" is set forth, the meaning of "EU/g" is not explained anywhere in the provisional application, and it cannot be assumed to mean "endotoxin units per gram."

With regard to claim 14, Applicants are directed to column 9, lines 13-24 of Abraham.

Claims 7-10, and 16-20 are rejected under 35 U.S.C. 102(e) as anticipated by Abraham et al (US 5,993,844) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abraham et al (US 5,993,844) alone. Abraham reasonably discloses the claimed invention as explained supra but fails to clearly disclose the product-by-process steps recited in the claims. However, the claimed product appears to be identical to the product disclosed by Abraham such that the claimed invention is considered anticipated thereby.

Alternatively, since the present claims contain product-by-process limitations, it is not explicitly clear that the product resulting from these process steps results in a product that is identical or substantially identical to that of Abraham. However, even if the process steps result in a different product from that of Abraham, the Examiner asserts that the difference is slight such that the claimed invention would have been considered obvious in view of Abraham alone; see MPEP 2113 that is incorporated herein by reference thereto.

With regard to claim 16, the tela submucosa claimed is inherently present in the tissue of Abraham since the same tissue as claimed is purified by Abraham.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al (US 5,993,844) alone. Abraham meets the claim language as explained in the rejection of base claim 1, but fails to disclose a tubular, tendon, or ligament form of the implant matrix. However, the Examiner asserts that a tubular, tendon, or ligament form of the Abraham implant matrix would have been considered obvious to an ordinary artisan since any body part (see column 4, lines 31-48) including tubular or ligament tissues (arteries, veins, intestines, heart valves, dermis, and ligaments; see column 8, lines 55-57) can be used to replace any portion of the patient's body in need thereof.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al (US 5,993,844) in view of Braun (US 3,562,820). Abraham meets the claim language as explained in the rejection of base claim 1 but fails to disclose strips of submucosa fused together as claim. However, Braun teaches that it was known to use strips of tissue fused together to form implants; see the abstract and the figures. Therefore, it is the Examiner's position that it would have been obvious to fuse two or more strips of the Abraham tissue matrix together in order to make a stronger or thicker

tissue implant to adapt it to the implant site as implicitly suggested by Braun.

### ***Interference Sought***

It is noted that the Applicant are seeking to provoke an interference with another assignee of the same subject matter. As of August 12, 2004, an Applicant seeking to provoke an interference has been required to provide the information required by new rule 37 CFR 41.202; see the attached sheet from the Federal Register, Vol. 69, No. 155, published August 12, 2004. Although an Applicant may have filed or attempted to provoke an interference prior to this date, it is the Examiner's understanding that the Board of Patent Appeals and Interferences is requiring all Applicants to comply with the new rule regardless of when the attempt was first presented.

With regard to the elements of Rule 37 CFR 41.202, particular attention is required for sections (a)(4) and (d). Failure to provide a thorough account of these items may result in delay in the process or in failure to prevail in decision.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.


Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Paul Prebilo  
Primary Examiner  
Art Unit 3738

  
Dir 3738

the scope of admissible proofs on priority. Where there is more than one count, each count must describe a patentably distinct invention.

*Involved claim* means, for the purposes of 35 U.S.C. 135(a), a claim that has been designated as corresponding to the count.

*Senior party* means the party entitled to the presumption under § 41.207(a)(1) that it is the prior inventor. Any other party is a *junior party*.

*Threshold issue* means an issue that, if resolved in favor of the movant, would deprive the opponent of standing in the interference. Threshold issues may include:

(1) No interference-in-fact, and  
(2) In the case of an involved application claim first made after the publication of the movant's application or issuance of the movant's patent:

(i) Repose under 35 U.S.C. 135(b) in view of the movant's patent or published application, or

(ii) Unpatentability for lack of written description under 35 U.S.C. 112(1) of an involved application claim where the applicant suggested, or could have suggested, an interference under § 41.202(a).

#### § 41.202 Suggesting an Interference.

(a) *Applicant*. An applicant, including a reissue applicant, may suggest an interference with another application or a patent. The suggestion must:

(1) Provide sufficient information to identify the application or patent with which the applicant seeks an interference,

(2) Identify all claims the applicant believes interfere, propose one or more counts, and show how the claims correspond to one or more counts,

(3) For each count, provide a claim chart comparing at least one claim of each party corresponding to the count and show why the claims interfere within the meaning of § 41.203(a),

(4) Explain in detail why the applicant will prevail on priority,

(5) If a claim has been added or amended to provoke an interference, provide a claim chart showing the written description for each claim in the applicant's specification, and

(6) For each constructive reduction to practice for which the applicant wishes to be accorded benefit, provide a chart showing where the disclosure provides a constructive reduction to practice within the scope of the interfering subject matter.

(b) *Patentee*. A patentee cannot suggest an interference under this section but may, to the extent permitted under § 1.99 and § 1.291 of this title, alert the examiner of an application

claiming interfering subject matter to the possibility of an interference.

(c) *Examiner*. An examiner may require an applicant to add a claim to provoke an interference. Failure to satisfy the requirement within a period (not less than one month) the examiner sets will operate as a concession of priority for the subject matter of the claim. If the interference would be with a patent, the applicant must also comply with paragraphs (a)(2) through (a)(6) of this section. The claim the examiner proposes to have added must, apart from the question of priority under 35 U.S.C. 102(g):

(1) Be patentable to the applicant, and  
(2) Be drawn to patentable subject matter claimed by another applicant or patentee.

(d) *Requirement to show priority under 35 U.S.C. 102(g)*. (1) When an applicant has an earliest constructive reduction to practice that is later than the apparent earliest constructive reduction to practice for a patent or published application claiming interfering subject matter, the applicant must show why it would prevail on priority.

(2) If an applicant fails to show priority under paragraph (d)(1) of this section, an administrative patent judge may nevertheless declare an interference to place the applicant under an order to show cause why judgment should not be entered against the applicant on priority. New evidence in support of priority will not be admitted except on a showing of good cause. The Board may authorize the filing of motions to redefine the interfering subject matter or to change the benefit accorded to the parties.

(e) *Sufficiency of showing*. (1) A showing of priority under this section is not sufficient unless it would, if unrebutted, support a determination of priority in favor of the party making the showing.

(2) When testimony or production necessary to show priority is not available without authorization under § 41.150(c) or § 41.156(a), the showing shall include:

(i) Any necessary interrogatory, request for admission, request for production, or deposition request, and

(ii) A detailed proffer of what the response to the interrogatory or request would be expected to be and an explanation of the relevance of the response to the question of priority.

#### § 41.203 Declaration.

(a) *Interfering subject matter*. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered

obvious the subject matter of a claim of the opposing party and vice versa.

(b) *Notice of declaration*. An administrative patent judge declares the patent interference on behalf of the Director. A notice declaring an interference identifies:

(1) The interfering subject matter;  
(2) The involved applications, patents, and claims;  
(3) The accorded benefit for each count; and  
(4) The claims corresponding to each count.

(c) *Redeclaration*. An administrative patent judge may redeclare a patent interference on behalf of the Director to change the declaration made under paragraph (b) of this section.

(d) A party may suggest the addition of a patent or application to the interference or the declaration of an additional interference. The suggestion should make the showings required under § 41.202(a) of this part.

#### § 41.204 Notice of basis for relief.

(a) *Priority statement*. (1) A party may not submit evidence of its priority in addition to its accorded benefit unless it files a statement setting forth all bases on which the party intends to establish its entitlement to judgment on priority.

(2) The priority statement must:

(i) State the date and location of the party's earliest corroborated conception,

(ii) State the date and location of the party's earliest corroborated actual reduction to practice,

(iii) State the earliest corroborated date on which the party's diligence began, and

(iv) Provide a copy of the earliest document upon which the party will rely to show conception.

(3) If a junior party fails to file a priority statement overcoming a senior party's accorded benefit, judgment shall be entered against the junior party absent a showing of good cause.

(b) *Other substantive motions*. The Board may require a party to list the motions it intends to file, including sufficient detail to place the Board and the opponent on notice of the precise relief sought.

(c) *Filing and service*. The Board will set the times for filing and serving statements required under this section.

#### § 41.205 Settlement agreements.

(a) *Constructive notice; time for filing*. Pursuant to 35 U.S.C. 135(c), an agreement or understanding, including collateral agreements referred to therein, made in connection with or in contemplation of the termination of an interference must be filed prior to the termination of the interference between